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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,686	10/01/2001	Michael Austin	S63.2-10142	1843

490 7590 10/30/2003

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

JIMENEZ, MARC QUEMUEL

ART UNIT PAPER NUMBER

3726

DATE MAILED: 10/30/2003

213

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/966,686

Applicant(s)

AUSTIN, MICHAEL

Examiner

Marc Jimenez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46,47,50-56,58-64,67-73 and 76-79 is/are rejected.
- 7) ☒ Claim(s) 48,49,57,65,66,74 and 75 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 19.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/16/03 has been entered.

Specification

2. The abstract of the disclosure is objected to because a new abstract is required that is indicative of which the claims are directed (ie. the method). Correction is required. See MPEP § 608.01(b).

3. The disclosure is objected to because of the following informalities:

- - now patent number 6,360,577 - - should be inserted after "September 22, 1999," in the first line of the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

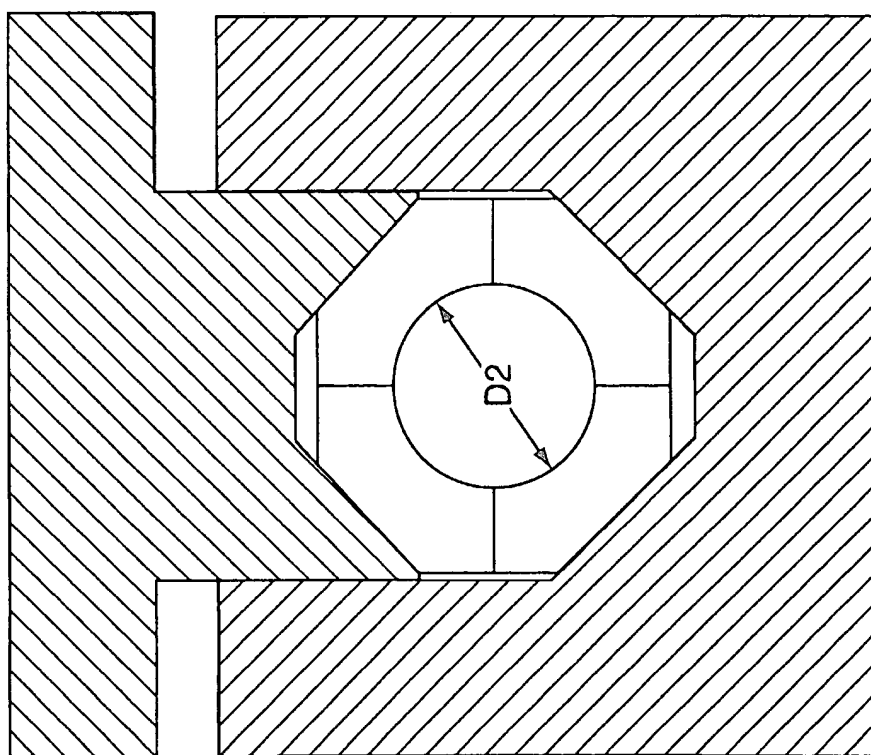
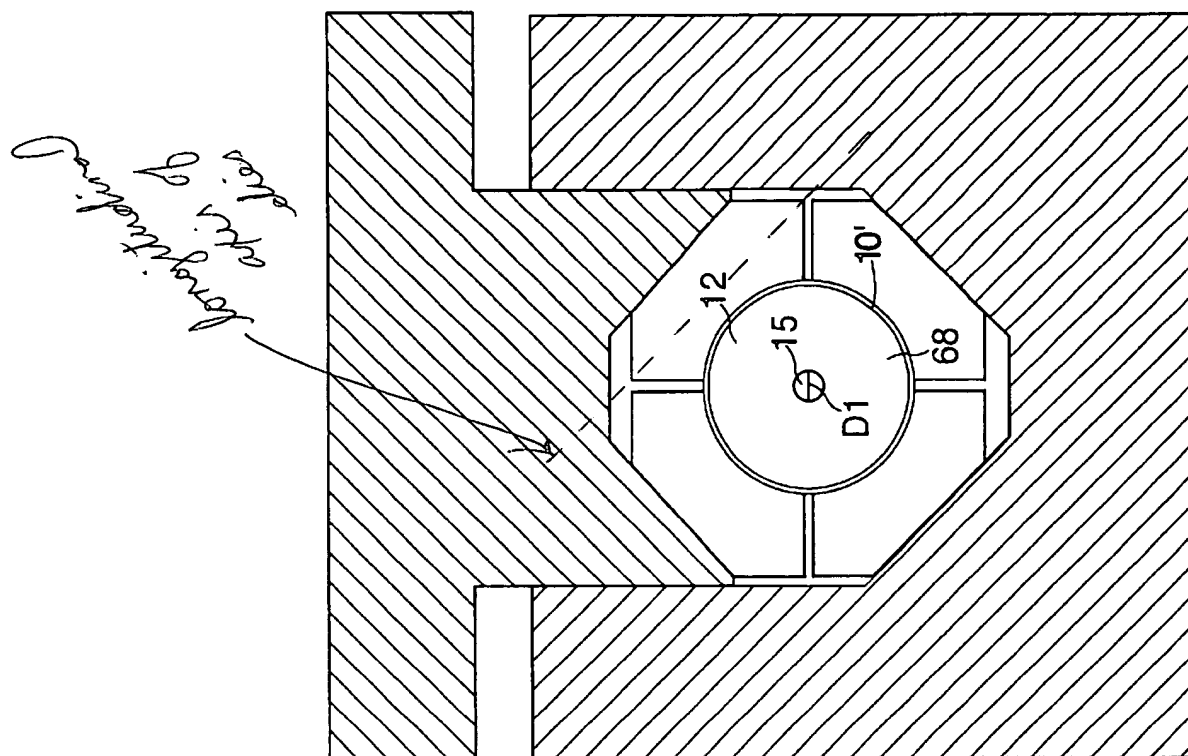
5. **Claims 46, 47, 50, 53, and 54** are rejected under 35 U.S.C. 102(e) as being anticipated by Pinchasik (6,364,870).

Pinchasik teaches a method of reducing a stent **4** in cross-section comprising the steps of: providing a crimper (for example, fig. 12-15) having a plurality of closely spaced movable dies **29-32** defining an aperture **15**, the dies **29-32** arranged to form an iris, the iris having an aperture **15** which is reducible in size by moving the dies **29-32**, the aperture **15** having a center, each of the dies **29-32** having a longitudinal axis (the "longitudinal axis" of the dies **29-32** is considered the imaginary line that goes from the edges which are at the furthest distance from each other of the dies **29-32** looking at fig. 15 see attached copy of fig. 5) which is tangent to the aperture **15**, placing a stent **4** disposed about a catheter **2** within the aperture **15** crimping the stent **4** onto the catheter **2** by reducing the size of the aperture **15**.

Regarding claim 47, the stent **4** is disposed about a medical balloon, the medical balloon disposed about a catheter **2** (abstract, lines 1-2).

Regarding claim 50, the dies **29-32** are wedge shaped (see edges near numerals **10'** and **68** in fig. 15).

Regarding claim 53, the dies **29-32** are moved cooperatively inward during the moving step.



Regarding claim 54, the entirety of the stent 4 is disposed in the aperture 15 during the placing step.

6. **Claims 55, 56, 59, 62-64, 67, 70, and 71** are rejected under 35 U.S.C. 102(b) as being anticipated by Morales (5,893,852).

Morales teaches a method of crimping a stent 10 comprising the steps of: providing a crimper 22 having a plurality of movable dies 30 arranged to form an iris 70 (note also that more than 4 dies could be used, therefore, defining an “iris” even more, see col. 9, line 24) having an aperture 66 which is reducible in size, each of the dies 30 having an inward facing straight side 62 (col. 7, lines 64-65, “rectangular” has a straight side) which faces the aperture 66, placing a stent 10 disposed about a catheter (col. 8, line 63) within the aperture 66, the inward facing straight sides 62 (col. 7, lines 64-65) of the dies 30 facing the stent 10, reducing the size of the aperture 66 and contacting the inward facing straight sides 62 (col. 7, lines 64-65) of the dies 30 against the stent 10 so as to crimp the stent 10 onto the catheter 11.

Regarding claims 56 and 64, the stent 10 is disposed about a medical balloon 14, the medical balloon 14 disposed about a catheter 11.

Regarding claims 59 and 67, the dies 30 are wedge shaped (see fig. 7B).

Regarding claim 62, the entirety of the stent 10 is disposed in the aperture 66 during the placing step (see fig. 2).

Regarding claim 63, Morales teaches that the dies 30 are in mechanical communication with an actuator 26, rotary motion of the actuator 26 causing the aperture 66 to increase in size or

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decrease in size, applying rotary motion to the actuator **26** to reduce the size of the aperture **66** to sufficiently contact the dies **30** against the stent **10** and reduce the stent **10** in cross section.

Regarding claim 70, the dies **30** are moved inward during the moving step.

Regarding claim 71, the entirety of the stent is disposed in the aperture during the placing step (see fig. 2).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. **Claims 58** is rejected under 35 U.S.C. 103(a) as being unpatentable over Morales in view of Myers et al. (5,700,285).

Morales teaches the invention cited with the exception of the stent being made of nitinol.

Myers et al. teach that it is known to use nitinol stents (col. 4, line 51).

It would have been obvious to one of ordinary skill in the art, at the time of the invention, to have provided the invention of Morales with a stent made of nitinol, in light of the teachings of Myers et al., in order to provide a stent material that that has good strength and corrosion resistant properties.

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9. **Claims 60, 61, 68, 69, 72, 73, and 76-79** are rejected under 35 U.S.C. 103(a) as being unpatentable over Morales.

Morales teach the invention cited with the exception of having at least 8 or 16 dies.

It is noted, however, that Morales suggests that more dies could be used (col. 9, lines 23-24) than the number disclosed.

At the time of the invention, it would have been an obvious matter of design choice to a person of ordinary skill in the art, to have used at least 8 or 16 dies because applicant has not disclosed that at least 8 or 16 dies provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with either the number of dies taught by Morales or the claimed at least 8 or 16 dies because either number of dies perform the same function of crimping equally well. Therefore, it would have been an obvious matter of design choice to modify Morales to obtain the invention as specified in claims 60, 61, 68, and 69.

10. **Claims 51 and 52** are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchasik.

Pinchasik teaches the invention cited with the exception of having at least 8 or 16 dies.

At the time of the invention, it would have been an obvious matter of design choice to a person of ordinary skill in the art, to have used at least 8 or 16 dies because applicant has not disclosed that at least 8 or 16 dies provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with either the number of dies taught by Pinchasik

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or the claimed at least 8 or 16 dies because either number of dies perform the same function of crimping equally well. Therefore, it would have been an obvious matter of design choice to modify Pinchasik to obtain the invention as specified in claims 51 and 52.

Allowable Subject Matter

11. **Claims 48, 49, 57, 65, 66, 74, and 75** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

12. Applicant's arguments with respect to claims 46-79 have been considered but are moot in view of the new ground(s) of rejection.

Contact Information

13. Telephone inquiries regarding the status of applications or other general questions, by persons entitled to the information, should be directed to the group clerical personnel. In as much as the official records and applications are located in the clerical section of the examining groups, the clerical personnel can readily provide status information. M.P.E.P. 203.08. The Group clerical receptionist number is (703) 308-1148.

If in receiving this Office Action it is apparent to applicant that certain documents are missing, e.g., copies of references cited, form PTO-1449, form PTO-892, etc., requests for copies of such papers or other general questions should be directed to Tech Center 3700 Customer

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Service at (703) 306-5648, or fax (703) 872-9301 or by email to

CustomerService3700@uspto.gov.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc Jimenez whose telephone number is **703-306-5965**. The examiner can normally be reached on **Monday-Friday, between 5:30 am- 2:00 pm**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Vo can be reached on 703-308-1789. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

Other helpful telephone numbers are listed for applicant's benefit.

Allowed Files & Publication	(703) 308-6789 or (888) 786-0101
Assignment Branch	(703) 308-9723
Certificates of Correction	(703) 305-8309
Drawing Corrections/Draftsman	(703) 305-8404/8335
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PCT Help Desk	(703) 305-3257

If the information desired is not provided above, or a number has been changed, please call the general information help line below.

Information Help line	1-800-786-9199
Internet PTO-Home Page	http://www.uspto.gov/


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MJ
October 29, 2003